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## NOTICE OF ALLOWANCE AND FEE(S) DUE

57339 7590 09/04/2008

CIMA  
LERNER, DAVID ET AL  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/04/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/661,693

09/14/2000

Sathasivan Indiran Pather

CIMA 3.0-030 CONT II

2096

TITLE OF INVENTION: SUBLINGUAL BUCCAL EFFERVESCENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$0	\$0	\$1440	12/04/2008

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

57339 7590 09/04/2008

**CIMA  
LERNER, DAVID ET AL  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090**

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,693	09/14/2000	Sathasivan Indiran Pather	CIMA 3.0-030 CONT II	2096

TITLE OF INVENTION: SUBLINGUAL BUCCAL EFFERVESCENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$0	\$0	\$1440	12/04/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
RAMACHANDRAN, UMAMAHESWARI	1617	424-434000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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09/661,693	09/14/2000	Sathasivan Indiran Pather	CIMA 3.0-030 CONT II	2096
57339	7590	09/04/2008	EXAMINER	
CIMA LERNER, DAVID ET AL 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			RAMACHANDRAN, UMAMAHESWARI	
			ART UNIT	PAPER NUMBER
			1617	
			DATE MAILED: 09/04/2008	

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/661,693	PATHER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	UMAMAHESWARI RAMACHANDRAN	1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/27/2008.
2. ☒ The allowed claim(s) is/are 22, 25, 27, 30-33, 83, 86, 88, 91, 93, 94, 105, 106-110 will be renumbered as 1-19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date <u>5/23/200</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|--|

### **DETAILED ACTION**

The examiner notes the receipt of the amendments and remarks received in the office on 5/27/2008. The claims 1-21, 23-26, 28, 29, 34-82, 84-85, 87, 89, 90, 92, 95-104 have been cancelled and claims 106-110 have been added new. Claims 22, 25, 27, 30-33, 83, 86, 88, 91, 93, 94, 105, 106-110 are free of prior art and are ready for allowance. The claims will be renumbered as 1-19.

### **Application Priority**

The present application is a continuation application of United States Patent Application No. 09/277,424 filed March 26, 1999 (Abandoned). The present invention claims the benefit of the United States Provisional Application No. 60/079 652 filed on March 27, 1998 and the claim for priority is acknowledged.

### **REASONS FOR ALLOWANCE**

The provisional rejection of claims 22, 25-27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 11/026,132 ('132), the provisional rejection of claims 22, 25-27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 11/027,353 ('353), the provisional rejection of Claims 22, 25-27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27, 29-33 of copending Application No. 11, 511, 098 ('098), the provisional rejection of Claims 22, 30, 33, 91, 93, 94, 105 rejected under the

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judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 15 of copending Application No. 11, 521, 796 ('796) are withdrawn because the instant application is the earlier filed application of all the pending applications.

The rejection of claims 22, 26, 27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 under 35 U.S.C. 103(a) as being unpatentable over McCarty (US 5,073,374) in view of Wehling et al. (WO 91104757) and further in view of Streisand et al. (Buccal absorption of fentanyl is pH-dependent in dogs', Anesthesiology, (1995 Mar), 82 (3), pp. 759-64), the rejection of claims 22, 26, 27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 under 35 U.S.C. 103(a) as being unpatentable over Wehling et al. (WO 91104757) in view of McCarty (US 5,073,374) and further in view of Streisand et al. (Buccal absorption of fentanyl is pH-dependent in dogs', Anesthesiology, (1995 Mar), 82 (3), pp. 759-64), the rejection of claims 22, 26, 27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 under 35 U.S.C. 103(a) as being unpatentable over Streisand (Anesthesiology, 1991, 75(2), 223-9) in view of Streisand et al. (Buccal absorption of fentanyl is pH-dependent in dogs', Anesthesiology, (1995 Mar), 82 (3), pp. 759-64) and further in view of Wehling et al. (WO 91104757), the rejection of claims 22, 26, 27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 under 35 U.S.C. 103(a) as being unpatentable over Norling et al (U.S. 5,958,458) in view of Wehling et al. (WO 91104757), the rejection of claims 22, 25-27, 30-33, 83, 84, 86, 88, 91, 93, 94 and 105 under 35 U.S.C. 103(a) as being unpatentable over Chen et al. ('Studies on formulations of fentanyl buccal adhesive tablets', Zhongguo Yiyao Gongye Zazhi, 1997, 28(3), 129-1311) in view of Wehling et al. (WO 91104757) and

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further in view of Streisand et al. ("Buccal absorption of fentanyl is pH-dependent in dogs", *Anesthesiology*, (1995 Mar), 82 (3), pp. 759-64) are withdrawn in view of the declaration dated 4/25/2006 and applicants arguments/remarks dated 5/27/2008.

The following is an examiner's statement of reasons for allowance:

Claims 22, 25, 27, 30-33, 83, 86, 88, 91, 93, 94, 105, 106-110 are drawn to a tablet comprising a pharmaceutically effective amount of fentanyl for oral administration across the oral mucosa, including buccal, sublingual and gingival administration, at least one pH adjusting substance, at least one saliva activated effervescent couple, up to 20 % weight of a non-effervescent disintegration agent. The closest prior art of record to the claimed invention are McCarty (US 5,073,374), Wehling et al. (WO 91104757), Streisand et al. (Buccal absorption of fentanyl is pH-dependent in dogs', *Anesthesiology*, (1995 Mar), 82 (3), pp. 759-64), Streisand (*Anesthesiology*, 1991, 75(2), 223-9) Norling et al (U.S. 5,958,458) and Chen et al. ('Studies on formulations of fentanyl buccal adhesive tablets', *Zhongguo Yiyao Gongye Zazhi*, 1997, 28(3), 129-1311).

McCarty et al. teaches fast dissolving buccal tablets particularly useful for the administration of active ingredients that show poor bioavailability upon administration through non-parenteral modes and such active ingredients include analgesics such as fentanyl. The prior art does not teach the effervescent couple or the pH adjusting substance in the composition. Wehling et al. teach effervescent dosage forms for direct oral administration comprising 5 to about 50 % effervescent disintegration agents (a soluble acid source and a carbonate source) and adjuvants such as binders, flavors,

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colors, fillers, non-effervescent disintegrants, etc. The reference teaches that analgesics are among the drugs that can be administered in oral effervescent dosage forms. The reference teach that the effervescence disintegration agent is present in an amount effective to aid in disintegration of the tablet, and to provide distinct sensation of effervescence when the tablet is placed in the mouth of a patient. The reference does not teach an oral transmucosal tablet and the pH adjusting substance and fentanyl as the specific analgesic in the effervescent dosage form. Streisand et al. teach that the buccal absorption, bioavailability and permeability of fentanyl are pH dependent and increase as the pH of the fentanyl solution becomes more basic, which is due to an increase in the fraction of unionized fentanyl. The reference does not teach a oral transmucosal tablet or the effervescent couple in the composition. The reference teaches that a pH adjusting substance added to fentanyl enhances absorption of the drug. Applicants' by declaration by Dr. Vikas Agarwal show unexpected results that a composition comprising fentanyl, effervescent couple and pH adjusting substance has superior permeability values when compared to addition of effervescent couple or pH adjusting substance to fentanyl. The data showed by the applicants in the declaration teach that the claimed combination of fentanyl, an effervescent agent and a pH adjusting substance was superior to the composition with fentanyl and pH adjusting substance or fentanyl and effervescent agent alone. The permeability value of fentanyl + effervescent couple + pH adjusting substance was 95.6 % (400% greater than the formulation with only one of the two required components) compared to fentanyl + effervescent couple 23.3 %, compared to fentanyl + pH adjusting substance 18.7%.

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Hence the claims of the instant invention are allowable in view of the unexpected results shown by the applicants in formulating fentanyl with the effervescent couple and pH adjusting substance. Norling et al. teach active substances in particulate formulations comprising effervescent disintegrants, a pharmaceutically inert carrier such as magnesium carbonate. Fentanyl is one of the active substances in the array of active substances listed in the reference. Norling et al. does not teach in any examples a formulation comprising fentanyl, effervescent couple and pH adjusting substance nor does it teach the amount of the disintegrating agents. One having ordinary skill in the art would not have any motivation to pick fentanyl from the list of active substances from Norling's teachings. Chen teaches fentanyl citrate buccal adhesive tablets. Chen et al. do not teach the effervescent couple or the pH adjusting substance in the formulation. As stated above, in view of the Applicants' declaration the claims are allowable over the prior art of record as unexpected results are shown in formulating fentanyl with the effervescent couple and pH adjusting substance. Applicants' have shown by declaration that the combination of a pH adjusting substance and an effervescent agent with fentanyl is superior to the use of either alone in an otherwise identical formulation.

The claims are allowable over the closest art of record because they do not teach or disclose the claimed formulation of fentanyl with a pH adjusting substance and an effervescent agent.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617